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U.S. DISTRICT COURT
N.D. OF ALABAMA

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

EDWIN R. BANKS,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	**Civil Action No.**
XAVIER BECERRA, in his official capacity as Secretary of the U.S. Department of Health and Human Services,	)	**5:20-CV-0565-LCB**
	)	
	)	
	)	
	)	
Defendant.	)	

DEFENDANT'S RESPONSE TO
PLAINTIFF'S "BRIEF RE: STANDING"

I. INTRODUCTION

This case involves judicial review of the denial of Medicare claims for certain months of tumor treatment field therapy ("TTFT") for Plaintiff Banks, who suffers from an aggressive form of brain cancer called glioblastoma multiforme (GBM). Following remand from the Eleventh Circuit, Banks claims that he has standing based on three grounds. Pl. "Brief re: Standing" (Doc. 67). But all three grounds upon which Banks claims to have standing collapse under scrutiny. First, Banks is not entitled to the specific Medicare benefits in question, as he asserts, and thus has suffered no injury in fact by paying Medicare premiums without receiving what he alleges are the "promised" benefits thereof. Second, contrary to Banks's argument, the Supreme Court has held that the mere violation of a statutory right cannot confer standing, and in any event the Eleventh Circuit has already rejected that argument in this case. Third, Banks cannot demonstrate a substantial risk of future injury because, by his own concession in his brief, he has ceased receiving TTFT treatments, and the future payment for such treatments forms the basis for his claims of future injury. Defendant's motion to dismiss should thus be granted because Banks cannot demonstrate that he has standing to bring suit.

II. ARGUMENT

A. Banks Is Not Entitled to Receive Medicare Benefits.

Banks asserts that he is "entitled" to certain Medicare benefits that provide coverage for TTFT treatments, and thus claims standing on the grounds that he has suffered injury in fact by paying Medicare premiums and not receiving payment for his TTFT treatments. Pl. Brief (Doc. 67) at 2, 4. Banks's argument misinterprets the applicable statutes.

The principal statute that Banks cites in support of this argument explicitly makes this claimed "entitlement" conditional: "The Secretary shall . . . make . . . [t]he initial determination of **whether** an individual is entitled to benefits under [Medicare Part A or Part B]." 42 U.S.C. §§ 1395ff(a)(1)(A) (emphasis added). The statute dictates, without ambiguity, that it is at the Secretary's discretion "whether" an individual is "entitled" to benefits in a given circumstance; no such "entitlement" is automatically conferred. "The language and punctuation Congress used cannot be read in any other way." *United States v. Ron Pair Enterprises, Inc.*, 489 U.S. 235, 242 (1989).

"[W]hen interpreting a statute, [the Court should] operate under the assumption that Congress says what it means and means what it says." *Kehoe v. Fid. Fed. Bank & Tr.*, 421 F.3d 1209, 1216 (11th Cir. 2005); *see also Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1725 (2017) (same). The Court

"'must construe [the] statute to give effect, if possible, to every word and clause.'" *Bishop v. Ross Earle & Bonan, P.A.*, 817 F.3d 1268, 1272 (11th Cir. 2016) (quoting *Lowery v. Ala. Power Co.*, 483 F.3d 1184, 1204 (11th Cir. 2007)); However, "[i]f the statute's meaning is plain and unambiguous, there is no need for further inquiry." *United States v. Fisher*, 289 F.3d 1329, 1338 (11th Cir. 2002) (internal quotations omitted). Reviewing "every words and clause" of 42 U.S.C. §§ 1395ff(a)(1)(A), there is no ambiguity that entitlement to benefits is contingent upon the Secretary's discretion.

While research did not uncover a case where the Eleventh Circuit has addressed the Secretary's discretion under § 1395ff, the Seventh Circuit has, and its ruling comports with the Secretary's position. In *Prosser v. Becerra*, 2 F.4th 708 (7th Cir. 2021), the facts are substantively identical to those here. As summarized by the Seventh Circuit,

> Prosser suffers from an aggressive brain cancer called glioblastoma multiforme. To treat her disease, Prosser uses a promising electric field treatment called tumor treating fields therapy. She will receive this therapy for the rest of her life. To pay for the therapy, Prosser enrolled in the supplemental insurance program within Medicare Part B. She files a benefits claim with Medicare for each period she receives [TTFT]. Medicare denied coverage for the treatment period January to April 2018. Though Prosser received the therapy and owed nothing out of pocket, the denial left the supplier of the treatment, Novocure, Inc., with the bill. Prosser challenged this denial by availing herself of Medicare's multilayer appeals process, losing at each level and eventually reaching federal court.

Id. at 710. The district court dismissed Prosser's claim for Medicare Part B coverage, holding that she has suffered no injury-in-fact sufficient to satisfy Article III's standing requirement. *Id.*

On appeal, Prosser claimed "a substantive statutory right to payment by Medicare," such that denial of coverage for the treatment at issue "infringe[d] that substantive right and therefore amounts to an injury for Article III standing purposes." *Id.* at 714. In rejecting this argument, the Seventh Circuit found that "Congress, in enacting Medicare, did not endow an individual with a substantive right to payment by Medicare each and every time they submit a claim. After all—and as the facts here show—Medicare payments most often go to the supplier or provider, not the recipient of care." *Id.* The Seventh Circuit then affirmed the district court's dismissal of Prosser's claim, stating

> Prosser received—and continues to receive—[TTFT]. She faces no financial liability for the treatment period Medicare denied coverage. And any future financial risk is too attenuated from the denial of the past coverage at issue here and far too speculative to establish standing. We therefore lack authority to hear Prosser's claim and affirm the dismissal of her complaint.

Id. at 710.

The Seventh Circuit's reasoning why Prosser was not entitled to Medicare benefits explains why Banks can cite no statute guaranteeing coverage for his TTFT claims—because none exists. To the contrary, coverage for durable medical

equipment (DME),[1] a category which includes the device that provides TTFT treatments, cannot be provided unless the device is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . . ." 42 U.S.C. § 1395y(a)(1)(A). The Supreme Court has foreclosed arguments that interfere with the Secretary's broad discretion to determine Medicare coverage, holding that the "Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which [he] implements h[is] decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler v. Ringer*, 466 U.S. 602, 617 (1984).

Viewed in that context, the stray words "entitle" or "entitlement" in various laws do not imply that Medicare is an open checkbook that must pay for every submitted claim. Indeed, as discussed, the statute that Banks principally relies on, 42 U.S.C. § 1395ff(a)(1), gives the Secretary broad authority to broaden or limit the scope of Medicare coverage. Section 1395ff(a)(1) authorizes the Secretary to "promulgate regulations and make initial determinations with respect to benefits" concerning "[t]he initial determination of whether an individual is entitled to benefits" as well as "[a]ny other initial determination with respect to a claim for

[1] The medical device that provides TTFT treatments is considered to be a type of "durable medical equipment" (DME) under Medicare Part B, which extends coverage to certain types of DME for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6).

benefits under such parts, including an initial determination by the Secretary that payment may not be made, or may no longer be made." *Id.* Given that the Secretary may determine that certain devices or claims are not covered, there is surely no "entitlement" for all claims to be paid.

However, Banks also cites 42 U.S.C. § 1395k(a), which contains definitions of the broad categories of medical and other services that may be eligible for Medicare coverage. But the only relevant definition is for "medical health and other services," which includes DME. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(6). DME must meet certain criteria to be eligible for Medicare coverage, and various conditions for payment also apply. *See* 42 U.S.C. § 1395l(e) (payment cannot be made unless beneficiaries submit adequately supported claims); 42 C.F.R. § 414.202 (requiring, inter alia, that DME must withstand repeated use and serve a medical purpose); *id.* § 410.38 (requiring, inter alia, a written order or prescription and supporting documentation).

In sum, Banks's interpretation of the Medicare laws is contrary to their plain language and the broader architecture of the Medicare program. Congress authorized beneficiaries to seek—but not necessarily to obtain—Medicare coverage for DME. There is no "entitlement" to TTFT coverage because Congress gave the Secretary broad discretion to approve or reject DME claims and established requirements that DME claims must satisfy to be eligible for coverage. And even if Banks's

interpretation of §§ 1395ff(a)(1) and 1395k(a) were correct, those provisions are inconsequential because Congress did not elevate a statutory violation to a "legally cognizable, concrete injury," much less grant a "plaintiff a cause of action to sue over the defendant's violation of that statutory prohibition or obligation." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021).

In sum, because the Secretary properly exercised his discretion to determine that TTFT treatments would not be funded through Medicare, Banks is not "entitled" to receive benefits in the form of payment for those treatments simply because he pays Medicare premiums. He cannot obtain standing on this ground.

B. Plaintiff Has Waived His Argument Premised Upon the Collateral Source Rule.

In the same section of his brief in which he asserts an "entitlement" to Medicare benefits, Banks also asserts standing based on the premise that the collateral source rule is applicable here insofar as the Secretary purports to argue that his "liability was offset to zero[ ] because Mr. Banks received [TTFT] treatment from Novocure." Pl. Brief (Doc. 67) at 6–7. The Secretary has not argued that. Regardless, Banks has waived any argument premised on the collateral source rule because it is not supported by citation to legal authority. "Issues raised in a perfunctory manner, without supporting arguments and citation to authorities, are

generally deemed to be waived." *N.L.R.B. v. McClain of Georgia, Inc.*, 138 F.3d 1418, 1422 (11th Cir. 1998).

While Banks's brief does include citations on the two pages that his collateral-source argument comprises, the authority he cites merely defines what the collateral source rule is (*see* Doc. 67 at 6) and supports his contention that it "is a feature of the federal common law" (*id.* at 7). Nowhere does he cite a single case from the Supreme Court, the Eleventh Circuit, or any other court that would actually develop or support his argument. This failure dictates that the argument has been waived. *See Sapuppo v. Allstate Floridian Ins. Co.*, 739 F.3d 678, 681 (11th Cir. 2014) ("We have long held that an appellant abandons a claim when he either makes only passing references to it or raises it in a perfunctory manner without supporting arguments and authority."); *Morgan v. Soc. Sec. Admin., Comm'r*, No. 4:17–cv–01148–ACA, 2019 WL 1466259, at *3 (N.D. Ala. Apr. 3, 2019) ("This sort of perfunctory argument gives neither the [defendant] nor the court any guidance about [Plaintiff's] argument aside from the fact that [she] asserts the existence of an error."); *Outlaw v. Barnhart*, 197 F. App'x 825, 828 n.3 (11th Cir. 2006) (finding claimant waived issue because he did not elaborate on it or cite any authority for it). Having waived this argument, Banks cannot rely on it in support of an assertion of standing.

C. A Statutory Violation Is Not Sufficient to Confer Standing.

Next, Banks claims that he has "standing based on the denial of his substantive statutory rights" under Medicare. Pl. Brief (Doc. 67) at 7–8. Yet the Eleventh Circuit has already rejected that argument in this case—and "ma[de] quick work of" it in doing so—because the argument "is foreclosed by circuit precedent." *Banks v. Sec'y of Health & Hum. Servs.*, No. 21-11454, 2021 WL 3138562, at *3 (11th Cir. July 26, 2021). Specifically, the appellate court stated,

> This Court has rejected the assertion that the allegation of a statutory violation alone is sufficient to confer standing. *See Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 924 (11th Cir. 2020) (en banc) ("[W]e know one thing to be true—alleging a mere statutory violation is not enough to show injury in fact."). Under *Muransky*, we instead must first ask if the statutory violation caused a direct harm to the plaintiff—if so, the plaintiff has stated an injury in fact. *Id.* at 926. In the absence of any direct harm, a plaintiff can still establish an injury in fact "by showing that a statutory violation created a 'risk of real harm.'" *Id.* at 927 (quoting *Spokeo* [*Inc. v. Robins*, 578 U.S. 330, 136 S. Ct. 1540, 1549 (2016)]). Banks's argument that the statutory violation itself is sufficient to confer standing fails because it overlooks these requirements. Novocure, and not Banks, is liable for the cost of the January, March, and April 2018 claims. Because he does not have to pay these claims, Banks has not shown how the statutory violation caused a direct harm.

Banks, 2021 WL 3138562, at *3.

This Court should therefore decline Banks's invitation to re-litigate an issue the Eleventh Circuit has already addressed and rejected, especially as Banks raises no new arguments to support it.

D. Banks Has No Standing Because He Is No Longer Receiving the Medical Treatments Which Could Result in His Alleged Future Injury, and He Has No Imminent Plans to Do So.

In the final section of his brief, Banks asserts standing on two inter-related grounds. First, he claims standing "based on the present loss of his right to the Medicare 'mulligan.'" *See* Pl. Brief (Doc. 67) at 12. Second, Banks asserts standing based on "substantial risk of future financial liability." *Id.*

For the benefit of the Court, what Banks calls the "mulligan" refers to an outcome that may result from the dictates of 42 U.S.C. § 1395pp. Thereunder, even if coverage for a device or service is denied, Medicare will still pay for the device/service if neither the beneficiary nor supplier knew, or reasonably should have known, that the claim would not be paid. *Id.* § 1395pp(a)(2). This statute is what Banks references as the "Medicare 'mulligan' provisions of 42 U.S.C. § 1395pp(a)" and, specifically, the one-time payment is what Banks references as the Medicare "mulligan." *See* Pl. Mot. for Discovery (Doc. 66) at 4; Pl. Brief (Doc. 67) at 3, 12–16. After receiving the one-time "mulligan" payment, the statute provides that "thereafter" the beneficiary will be charged with knowledge that future such claims will be denied and no longer qualify for payment under the provision. 42 U.S.C. § 1395pp(a)(2); *see also* 42 C.F.R. § 411.404(b) (beneficiary deemed to have knowledge).

In essence, Banks is arguing that because he has had TTFT claims denied and is therefore charged with the knowledge contemplated by 42 U.S.C. § 1395pp(a)(2), his loss of any future "mulligan" payment confers standing because if he submits another TTFT claim, it may be denied and he may be held financially liable. Pl. Brief (Doc. 67) at 15–16. As a matter of law, this claim is unduly speculative to sustain a claim for future injury for the reasons set forth in the Secretary's Motion to Dismiss (Doc. 65) at 14–18. But it is rendered wholly inactionable by Banks's **own concession that he is no longer receiving TTFT treatments**. In his brief, in a footnote on page 14, Banks's counsel states "Counsel understands from Mr. Banks that, against the advice of his doctors, Mr. Banks has elected to take a break from using the TTFT device but intends to resume use if his condition changes." Doc. 67 at 14 n.10. As expounded in the Secretary's motion to dismiss (*see* Doc. 65 at 12–14), if an injury is not "actual," it must be "imminent," which means "that the injury is certainly impending." *Lujan v. Defenders of Wildlife, et al.*, 504 U.S. 555, 564 n.2 (1992) (internal quotations omitted). Allegations of "an injury at some indefinite future time" are insufficient. *Id.* There could be no more paradigmatic definition of an injury which might happen at "some indefinite future time" than one which *could* transpire upon an individual *who isn't undertaking the action which might lead to the alleged injury, and has no imminent plans to do so, but could conceivably do so in the future*.

Banks's concession forecloses his own arguments in favor of standing. He is not receiving TTFT treatments, and he has no "imminent" plans to do so, meaning any hypothetical injury will take place, if at all, "at some indefinite future time." *See Lujan*, 504 U.S. at 564 n.2. As the Seventh Circuit put it, "any future financial risk is too attenuated from the denial of the past coverage at issue here and far too speculative to establish standing." *Prosser*, 2 F.4th at 710. No further analysis need be conducted. Any future injury is too speculative to support standing.

VI. CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that this Court grant his motion to dismiss for lack of subject-matter jurisdiction and dismiss this case in its entirety, with prejudice.

Date: October 18, 2021

Respectfully submitted,

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